PUBLICCITIZEN

Discovery of Problems With SUPPORT TRIAL and Flow of Information

Discovery of Problems

UNIVERSITY OF BIRMINGHAM

Professor Peter Brocklehurst
A lead investigator for the Boost II UK trial, similar to the SUPPORT trial. Sent an email alerting his. U.S. counterpart, Neil Finer, M.D., to problems with oxygen monitors that could endanger the infants enrolled in the UK and U.S. trials.

What happened to the information

UC San Diego

Neil Finer, M.D.
One of two national principal investigators for the SUPPORT trial. Was warned by Brocklehurst of the potential of the faulty oxygen monitors "to lead to harm."

Lead investigators
Finer informed multiple lead investigators at institutions enrolling subjects in the SUPPORT trial.

NIH National Institutes of Health
Turning Discovery Into Health

Rosemary Higgins
Lead National Institutes of Health staff member overseeing the SUPPORT trial. Learned of problems from Finer. Sent incomplete information to the Data and Safety Monitoring Committee chair.

Incomplete information

Gordon Avery, M.D., Ph.D.
Avery chaired the Data and Safety Monitoring Committee overseeing the SUPPORT trial. Avery was given incomplete information about the safety concerns surrounding the SUPPORT trial. The committee was created by the National Institutes of Health.

For more information on the SUPPORT trial, click here.

Entities with oversight responsibilities for protecting human research subjects*

*apparently were not informed

Institutional Review Boards
These boards reviewed and approved the trial at each participating hospital. Federal regulations require the prompt reporting to these boards of unanticipated problems involving risk to subjects in clinical trials.

Data and Safety Monitoring Committee members
The Data and Safety Monitoring Committee for the SUPPORT trial was charged with monitoring trial data periodically and look for risks to trial subjects.

Office for Human Research Protections
Federal regulations require the prompt reporting to this office of unanticipated problems involving risk to subjects in clinical trials.